



## PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference P61428PC00	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/NL 03/00616	International filing date (day/month/year) 03.09.2003	Priority date (day/month/year) 05.09.2002
International Patent Classification (IPC) or both national classification and IPC A61C13/00		
Applicant ELEPHANT DENTAL B.V.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"><li>I <input checked="" type="checkbox"/> Basis of the opinion</li><li>II <input type="checkbox"/> Priority</li><li>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li><li>IV <input type="checkbox"/> Lack of unity of invention</li><li>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li><li>VI <input type="checkbox"/> Certain documents cited</li><li>VII <input type="checkbox"/> Certain defects in the international application</li><li>VIII <input type="checkbox"/> Certain observations on the international application</li></ul>		
Date of submission of the demand  18.03.2004	Date of completion of this report  16.04.2004	
Name and mailing address of the international preliminary examining authority:   European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Thornton, S  Telephone No. +31 70 340-4182  	

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/NL 03/00616**

**1. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-16 as originally filed

**Claims, Numbers**

1-10 as originally filed

**Drawings, Sheets**

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-10
	No: Claims	
Inventive step (IS)	Yes: Claims	1-10
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-10
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

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**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**Novelty**

D1, EP-A-0 631 995, discloses a dental ceramic made by pressing a moulding composition of 1-50 wt% glass particles and 99-50 wt% inorganic oxide particles (e.g. yttria doped tetragonal zirconia - YTZP) at a pressure of 10-40 MPa and temperature 1000-1200 DEG C. The size of the particles are less than 35 um preferably less than 5 um. The ceramic can be treated further by veneering a coloured glass on the surface (see D1, page 9, line 16 - page 10, line 22; claims).

D2, EP-A-0 218 853, discloses YTZP sintered in two stages in oxidising atmosphere where the second stage is by hot isostatic pressing. To create a coloured ceramic a colourant, an inorganic pigment, can be added to the sintered material. The ceramic can be used for tooth crowns (see D2, column 3, line 14-21; column 13, line 9-21; examples; claims).

D3, US 2002/006532 A1, discloses a YTZP dental component. The grain size is less than 0.5 um. The ceramic is so treated to form a glassy phase and bonding surface (see D3, paragraphs 23,24; claims).

D4, US-A-5 833 464 (& DE-A-19630412 cited by applicant), discloses a process for the fabrication of a full-ceramic dental build-up on a zirconia root pin, wherein a zirconia glass is heat pressed against the root pin (see D4, column 4, line 34-43; column 5, line 8-40; claims).

None of the documents D1-D4 disclose a process for the preparation of a full-ceramic dental restoration, comprising heat pressing of a tooth coloured pressing glass on a fully or partially supporting structure of YTZP, with a grain size of less than 0.6 um, nor wherein the pressing glass has a thermal expansion coefficient of 9-11 um/mK or a pressing temperature of between 750-1000 °C. Therefore, the subject-matter of claims 1-10 of the present application meets the requirements of novelty.

**Inventive Step**

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International application No. PCT/NL03/00616

Document D1, which is considered to represent the most relevant state of the art, discloses a dental ceramic made by pressing a moulding composition of YTZP with a particle size less than 35  $\mu\text{m}$  preferably less than 5  $\mu\text{m}$  at a pressure of 10-40 MPa and temperature 1000-1200 DEG C and treated further by veneering a coloured glass on the surface from which the subject-matter of claim 1 differs in that in the present application the grain size is less than 0.6  $\mu\text{m}$ .

The problem to be solved by the present invention may therefore be regarded as an improved aesthetic ceramic dental restoration comprising heat pressing of a tooth coloured pressing glass on a supporting structure of YTZP. The problem of using a coarsely grained structure is that these grains contain significant residual intragranular porosity and a high sintering temperature is required which causes impurity diffusion at grain boundaries producing a significant glassy phase (cf. D3), thereby affecting mechanical properties. Coarse grains are more easily broken during adhesion testing, thereby lowering overall bond strength.

This problem is solved in the present application by the use of fine grained YTZP (the grain size, as measured by the linear intercept method, is less than 0.6  $\mu\text{m}$ ). The very fine microstructure of biomedical grade YTZP results in intragranular bonding and provides a surface suitable for bonding to heat-pressed glass (see application, page 11, line 11-23). Therefore, it would not be obvious for a person skilled in the art to select to come to such a solution in order to solve the problem posed. Therefore, the subject-matter of claims 1-10 involves an inventive step.